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10/527,301	03/09/2003	Frank M Fago	1628 WO/US	2534

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EXAMINER

BUI, LUAN KIM

ART UNIT

PAPER NUMBER

3728

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/527,301

Applicant(s)

FAGO ET AL.

Examiner

Luan K. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-7,10,11,13-19 and 22-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,10,11,13-19 and 22-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/1/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 5, 6, 17, 19, 22 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Yanke et al. (2003/014210; hereinafter Yanke'210). Yanke'210 discloses in the embodiment of Figure 13, a pharmaceutical pig (210) for holding a syringe of radiopharmaceutical liquid comprising a base (214) including a base shielding element made of a radiation blocking material and a base shell made of a polymer material that completely encloses the base shielding element and a cap (226) removably attached to the base. The cap comprises a cap shielding element (234) made of a radiation blocking material and a cap shell made of a polymer material that completely encloses the cap shielding element. The base defined a first hollow center section to receive the body portion of the syringe and the cap defined a second hollow center section to receive the plunger portion of the syringe.

As to claims 3 and 5, Yanke'210 discloses a small amount of relative rotation such as one-quarter of a turn is required to open and close the container (page 3, first column, paragraph 0033).

As to claim 6, see claim 18.

As to claim 17, Yanke'210 further discloses an o-ring (238) to provide a fluid tight seal between the cap and the base.

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As to claim 19, Yanke'210 discloses a protrusion disposed between the base shell near an open end (Figure 13).

As to claim 26, Yanke'210 discloses a shoulder adjacent to a cap engaging portion (270) for receiving the finger grip of the syringe.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 7, 22, 23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanke et al. (2003/014210; hereinafter Yanke'210) in view of Reich (5,672,883). Yanke'210 discloses in the embodiment of Figure 13, the pharmaceutical pig (210) for holding the syringe of radiopharmaceutical liquid as above having all the limitations of the claims except for the plastic material comprises polycarbonate resin. Reich shows a pharmaceutical pig comprising a base and a cap are made of plastic material and the plastic material includes polycarbonate resin. It would have been obvious to one having ordinary skill in the art in view of Reich to modify the

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pharmaceutical pig of Yanke'210 so the plastic material comprises polycarbonate resin for better protecting radiation or to reduce the cost of manufacture.

As to claims 22, 23 and 26, Yanke'210 discloses the first hollow center section in the base configured to receive the syringe body includes a needle. To the extent that Yanke'210 fails to show the first hollow center section configured to accommodate the syringe body includes the needle, it would have been obvious to one having ordinary skill in the art in view of Reich to modify the syringe of Yanke'210 so it includes a needle for better protecting the user during use.

6. Claims 10, 11, 13-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 22 above, and further in view of Fu et al.

(6,576,918; hereinafter Fu'918). Yanke'210 fails to show a bottom portion of the base being substantially bell-shaped with plurality of flattened portions and a bottom portion of the cap includes a plurality of flattened portions. Fu'918 discloses a pharmaceutical pig (10) comprising a base (18) including a bottom portion is substantially bell-shaped with a plurality of channels (98) and a top portion having a plurality of flattened portions (87) and a cap having a bottom portion with a plurality of flattened portions (59). It would have been obvious to one having ordinary skill in the art in view of Fu'918 to modify the shape of the pharmaceutical pig of Yanke'210 so the bottom portion of the base is substantially bell-shaped with a plurality of channels or flattened portions and the bottom portion of the cap includes a plurality of flattened portions to facilitate gripping the pig during opening and/or closing the pig and also the selection of the specific shape for the pharmaceutical pig would have been an obvious matter of design choice inasmuch as the resultant structures will work equally well and inasmuch as applicant's

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specification does not state that using these specific shapes as claimed solves any particular problem or yields any unexpected results.


7. Claims 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 2 and 22 above, and further in view of Hutcheson (6,781,142). Yanke'210 further fails to show at least one locking detent associated with the threads. Hutcheson suggests a radiation-shielding container comprising at least one locking detent (56, 70, 106, 110, 112) associated with threads in a base (14) and a cap (18). It would have been obvious to one having ordinary skill in the art in view of Hutcheson to modify the threads of Yanke'210 so it includes at least one locking detent for further securing the cap to the base.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is (571) 272-4552. If in receiving this Office Action, it is apparent to Applicant that certain documents are missing from the record for example copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to Ms. Errica Miller at (571) 272-4370.

Any inquiry of a general nature or relating to the status of this application should be directed to the Customer Service whose telephone number is (703) 306-5648. Facsimile correspondence for this application should be sent to (571) 273-8300 for Formal papers and After Final communications.

lkb  
August 28, 2005



Luan K. Bui  
Primary Examiner